# UNITED STATES PATENT AND TRADEMARK OFFICE

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/348,506 | 07/07/1999 | BOZIDAR FEREK-PETRIC | P-8027 | 5334 |

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| 27581     7590     12/02/2005 | | EXAMINER |
| MEDTRONIC, INC. | | PRIETO, BEATRIZ |
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| ART UNIT | PAPER NUMBER |
|---|---|
| 2142 | |

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DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|---|---|---|
| **Office Action Summary** | 09/348,506 | FEREK-PETRIC, BOZIDAR |
| | Examiner | Art Unit | |
| | Prieto B. | 2142 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)☒ Responsive to communication(s) filed on <u>05 October 2005</u>.

2a)☒ This action is **FINAL.**     2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)☒ Claim(s) <u>36-41</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>36-41</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

## Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>07 July 1999</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All  b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

## *Detailed Action*

1.      This communication is in response to Amendment filed 10/06/05, claims 36-41 have been examined and remain pending.

2.      Acknowledge is made to declaration filed pursuant to 37 C.F.R. 1.121 to nullify the applied art, which is seems to be applicable solely to the Bardy (US 6,312,378) having a filing data of June 3, 1999.

## *Claim Rejection under 35 U.S.C. 103*

3.      Quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action may be found in previous office action.

4.      Claims 36-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell U.S. Patent No. 5,720,771 in view of Frid et. al. (US 5,857,967) in further view of Comer, D., Internetworking with TCP/IP, Vol. I, Principles, Protocols and Architecture, 3erd Edition, 1995.

Regarding claim 36, Snell teaches a the system/method of Figs. 1-4;

        an implantable device (16) within a patient's body (col 4/lines 10-15), said implantable device capable of bi-directional communication with a "programmer" device (10) (receive-transmit, col 7/lines 16-25, 43-56);

        the programmer (10) in telemetry communication with said implantable device (col 4/lines 38-46, detect: col 7/lines 43-44, detect: col 8/lines 20-24, e.g. physiological conditions) in the patient;

        transmit and receiving data between the programmer and a "server" computer or host (12) (col 8/lines 61-66, col 2/lines 43-45, 54-59, col 9/lines 45-55) via a wireless communication medium (communication network) (col 9/lines 45-55) capable of bi-directional communication with said remote computer system (col 5/lines 27-36, send-receive, col 5/lines 2-27);

        although Snell discloses interconnecting physiological monitors (clients) to a central monitoring station (server), which allows the physical condition of many patients to be  monitored by a relatively small staff., where the communication between the monitors and the central station depend on the communication protocol used by the monitoring system (col 1/lines 22-34). Snell also discloses that multiple central monitoring stations for monitoring the physiological condition of patients in a hospital setting are well-known (col 5/lines 27-29), however does not teach a communicating via a first communication and second communication protocol.

Frid's disclosure related to medical devices, teaches a server functionality for providing access to medical information using open standard network protocol on a communication paths (Fig. 1, col 2/lines 13-36, col 5/lines 37-40);

transmitting and receiving a first data stream between the server (14) and a client computer (40) over a network (30) via a first communication protocol (col 3/lines 8-37), where the client computer transmits a request for medical information and receives from the server the requested information (col 3/lines 50-col 4/line 13, this is a bi-directional communication between a server and client via a communication protocol).

transmitting and receiving a second data stream between the server and the client computer over a network (30) via a second protocol (col 6/lines 45-51, col 3/lines 23-37);

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the suggestion of Snell for providing data obtained from the implantable device to the programmer and transmitted to a central monitoring station at a hospital facility for monitoring by staff therein, the teachings of Frid for providing access to medical information would be readily apparent. One would be motivation to utilize an open standard network protocol which does not have proprietary protocol requirements using hypermedia format (HTML/HTTP) maintain the communication interactive and thereby bi-directional as well as underlying protocol transport layers including TCP/IP as suggested by Frid.

However, although Snell teaches where the communication using a communication protocol, it is silent with respect to a specific protocol, namely to the acknowledgment required in under TCP/IP communication and the lack of acknowledgement require under UDP/IP;

Comer teaches a reliable stream delivery protocol (TCP) part of the TCP/IP suite (section 13.1 to 13.2) to transfer a stream of bits of data between two application programs executing on their respective sending or source machine and the recipient or destination machine, for sending a data stream from a source machine to a destination machine (section 13.3), this reliable protocol uses a acknowledgment technique, which requires the recipient to communicate across the network with the source, sending back an acknowledgment as it receives data from the source (see Figs. 13.1-13.2 & 13.4)(section 13.4-13.5);

the TCP/IP suite, the User Datagram Protocol (UDP) provides the similar capabilities as TCP in that it enables application programs running on a host computer to send stream bits (datagrams) to another application, each datagrams also including a destination/source address, making it possible for the UDP protocol software at the destination to deliver the message to intended recipient and for the recipient to send a reply, UDP uses IP to transport stream data from one host machine to another providing unreliable,

connection datagram delivery, it does not use acknowledgment to make sure the data stream arrived (section 12.3);

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Snell for transmitting data from the programmer to a remote server, office and/or database over the Internet, that the principals under which TCP/IP protocol suite communication operate will be implemented to establish communication between two or more computer. Thereby, any host or program executing on a machine with sending and receiving capabilities communicating under a reliable transport stream as TCP performs claimed functionalities, i.e. send a data stream and/or sending a receipt in response to received data stream in the case of TCP and transmitting and receiving data streams without sending receipts as in the case of UDP. The teachings of Comer do not modify the system or structure of Snell, they simply identify the communication principles suggested in Snell's system.

Regarding claim 37, TCP/IP contains the sender and destination IP address (Comer: see Fig. 13.7, source/destination port addresses on page 204).

Regarding claim 38, UDP/IP contains the recipients IP address (Comer: see Fig. 12.1 source and destination port address on page 181).

Regarding claim 39, wherein the data stream sent from the server is a signal retrieved by the programmer from the implanted device from the implantable device (Snell: col 4/lines 10-15), heart or cardiac related to the patients condition "real-time ECG waveform" (Snell: col 1/lines 13-21).

Regarding claim 41, the signal measured by the implanted device include electrocardiogram cardio signal "real-time ECG waveform" (col 1/lines 59-65), these signal, the collected cardiovascular measures set includes individual cardiovascular measures which each relate to patient information recorded by the cardiac monitoring device for an individual patient (Snell: col 1/lines 46-54).

7.      Claim 40 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell in view of Comer in further view of Moore et. al. (US 4,750,495).

Regarding claim 40, although Snell does not explicitly teach where the ECG, particularly, comprise QRS signals:

Moore teaches an electro cardio gram comprising QRS signal (col 3/lines 14-28).

It would have been obvious at the time the invention was made given the suggestion of Snell for retrieving electrocardiogram data from the pacemaker or a broad class of implantable device including from implantable devices such as cardiovascular monitors to sense electrical activity in the atrium and ventricle of the heart such as with QRS signals.

8.     Quotation of the second paragraph of 35 U.S.C. 112 may be found in previous office action. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this case, the term "crucial" in claim 40 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim will be given the broadest interpretation in light of the specification (see MPEP 2111). Applicant has indicated (p. 4) that the term "crucial" does <u>not</u> appear in any of the claims under examination.

*Response to arguments*

9.     Regarding claim 36, rejected under 103 as being unpatentable over Snell, it is argued (p. 7-9 of remarks) that the reference does not teach a bidirectional communication between a implantable medical device and an external station, because the term "bi-directional" precisely appears once in the reference and this doe not read on this notion.

In response to the above mentioned argument, applicant's interpretation of the applied prior art has been carefully considered. However, Snell discloses

Implantable cardiac stimulating devices, can **transmit** sensor measurements **to an external receiver** using telemetry, the external receiver is typically a "programmer" (external station), which can be used to program the settings of the cardiac stimulating device, a physician uses the **programmer to direct** a cardiac stimulating device to transmit the signals measured by sensors in the cardiac stimulating device, so that the programmer can analyze and display this data. (col 1/line 55-col 2/line 9)

This is a "bi-directional" communication between the implanted device and the programmer.

Further, Snell discloses: Data measured by an implantable medical device to be used to generate an alarm and to be **transmitted via telemetry** to a monitoring unit. (col 2/lines 34-38) and the

monitoring unit **receives physiological data** from cardiac stimulating devices and cardiac monitoring devices (col 2/lines 40-42); and

The implantable medical device 16 interacts with the monitoring unit 10 via telemetry, depending on the capabilities of the implantable medical device 16, **data and markers may be telemetered to** the monitoring unit 10 either periodically or continuously. If desired, the implantable medical device 16 can **be directed to transmit** information to the monitoring unit 10, regardless of whether any confirming **signals are received from** the monitoring unit 10. Alternatively, the transmission protocol can involve handshaking. If necessary, the monitoring unit 10 can **transmit a request for each item of data or marker that is sent from the implantable medical device 16**. Preferably, however, the implantable medical device 16 can be directed to **transmit data and markers to the monitoring unit 10 with a single command**. (col 7/lines 43-59)

This is a "bi-directional" communication between the implanted device and the programmer.


10.　　　Regarding claim 36, rejected under 103 as being unpatentable over Snell, it is argued (p. 7-9 of remarks) that the reference does not teach a bidirectional communication between the server and a client computer over a network via a first communication protocol.

In response to the above-mentioned argument, applicant's interpretation of the applied prior art has been considered. However, although Snell discloses interconnecting physiological monitors (clients) to a central monitoring station (server), which allows the physical condition of many patients to be monitored by a relatively small staff., where the communication between the monitors and the central station depend on the communication protocol used by the monitoring system (col 1/lines 22-34). Snell also discloses that multiple central monitoring stations for monitoring the physiological condition of patients in a hospital setting are well-known (col 5/lines 27-29), however does not teach a communicating via a first communication and second communication protocol.

Frid's disclosure related to medical devices, teaches a server functionality for providing access to medical information using open standard network protocol on a communication paths (Fig. 1, col 2/lines 13-36, col 5/lines 37-40); transmitting and receiving a first data stream between the server (14) and a client computer (40) over a network (30) via a first communication protocol (col 3/lines 8-37), where the client computer transmits a request for medical information and receives from the server the requested information (col 3/lines 50-col 4/line 13, this is a bi-directional communication between a server and client via a communication protocol), and transmitting and receiving a second data stream between the server and the client computer over a network (30) via a second protocol (col 6/lines 45-51, col 3/lines 23-37).

11.    Applicant's arguments filed with the above-mentioned amendment have been fully considered but not found persuasive.

12.    Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

## *Citation of Pertinent Art:*

13.    The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Copies of Non-Patent Literature documents cited will be provided as set forth in MPEP§ 707.05(a):

Long Range Closed Loop Telemetry for Research, Soykan, O., ET. AL., IEEE, 0-7803-3811-1, 1996, p. 280-281.

Soykan et. al. discloses a "bi-directional" communication between the implanted device and the programmer.

BEATRIZ PRIETO
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (571) 272-3902. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Andrew T. Caldwell can be reached at (571) 272-3868. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, status information for published application may be obtained from either Private or Public PAIR, for unpublished application Private PAIR only (see http://pair-direct.uspto.gov or the Electronic Business Center at 866-217-9197 (toll-free).

Any response to this action should be mailed to:
      Commissioner of Patents and Trademarks
      P.O. Box 1450
      Alexandria, VA 22313-1450

Hand carried or delivered to:
      Customer Service Window located at the Randolph Bldg.
      401 Dulany St.
      Alexandria, VA 22314

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      (571) 273-8300 (New Central Fax No.)

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B. Prieto
Primary Examiner
TC 2100
November 28, 2005

BEATRIZ PRIETO
PRIMARY EXAMINER